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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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EXAMINER

HINES, JANA A

ART UNIT PAPER NUMBER

1645

DATE MAILED: 03/01/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Applicati n No.

09/335,581

Applicant(s)

BANNAN ET AL.

Examiner

Ja-Na A Hines

Art Unit

1645

-- The MAILING DATE f this communication appears on the cover sheet with the correspondence address --
Period f r Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on 06 July 2001 and 15 November 2001.
- 2a) ☒ This action is FINAL. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disp sition of Claims

- 4) ☒ Claim(s) 50-55 is/are pending in the application.
- 4a) Of the above claim(s) 50-53 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 54 and 55 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 14.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

DETAILED ACTION

Amendment Entry

1. Amendments filed on July 6, 2001 and December 12, 2001 have been entered. Claims 50-55 have been amended. Claims 50-55 with respect to SEQ ID NO:3 and 34 only are under consideration in this office action.

Withdrawal of Rejections

2. The rejection of claims 54-55 under 35 U.S.C. 102(b) as being anticipated by Hoffman et al., Jet et al., or Soos et al., is withdrawn in view of applicants amendments.

NEW GROUNDS FOR REJECTION

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 50-55 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Applicants have

Art Unit: 1645

attempted to amend the specification and claims to include newly added sequences SEQ ID NO:32-80 and are retained after dialysis to remove molecules with molecular weights of less than 6000-8000 daltons with the proviso that the larger molecule is not SEB or SEC or other native toxin.

Neither the specification nor originally presented claims provides support for these sequences. Applicant has not pointed to support in the specification for the addition of these new sequences. Furthermore, there is no support in the specification which teaches a peptide consisting of the amino acid sequence SEQ ID NO:34. Also, there is no support for a peptide, either SEQ ID NO:3 or 34 which are retained after dialysis to remove molecules with molecular weights of less than 6000-8000 daltons with the proviso that the larger molecule is not SEB or SEC or other native toxin. Applicant has pointed to support at pages 2-4, 24, 63-64, and figure 3 which show that SEB and SEC are identified as being known in the art for containing the 12-mer sequences. None of these cited reference pages recite support for the proviso.

At page 24 lines 18-19, the specification states that the preferred peptides of the invention are those that exclude full length native toxin molecules, however the specification teaches the native toxins. The specification only provides for randomly cross-linked polymer peptides, and does not provide support for the specific sequences now recited, i.e., SEQ ID NO: 32-80. The genus described by consensus sequences does not inherently provide support for the addition of SEQ ID NO: 32-80. There is no specific written description of the individual combinations disclosed in SEQ ID NO:32-

Art Unit: 1645

80. Therefore, the amended claims incorporate new matter and are accordingly rejected.

- X 4. Claim 55 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Acronyms like SEB and SEC must be spelled out when used for the first time in a chain of claims.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

- X 5. Claims 50-55 are rejected under 35 U.S.C. 101 because the peptide is a product of nature. Thus such a peptide would be naturally produced. Claims 50-55 do not require the peptides to be isolated. Insertion of the terms "isolate or synthetic" would obviate this rejection. See also the 112, second paragraph of the previous office action.

Double Patenting

6. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

Art Unit: 1645

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

- x 7. Claims 50-55 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1 and 8 of U.S. Patent No. 6,075,119. Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims of the instant application are drawn to a peptide consisting essentially an amino acid sequence selected from SEQ ID NO: 3 or 34; and wherein the peptide is a component of a larger molecule which is retained after dialysis to remove molecules with molecular weights of less than 600-8000 daltons with the proviso that the larger molecule is not SEB or SEC or other native toxin. The claims of US Patent 6,075,119 are drawn to a peptide comprising at least one amino acid sequence selected from a group consisting of SEQ ID NO: 3; and wherein the peptide is a component of a larger molecule which is retained after dialysis to remove molecules with molecular weights of less than 600-8000 daltons. Thus, the claims of the instant application are encompassed by the claims of the US Patent and are therefore not patentably distinct.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

8. Claims 50-55 are rejected under 35 U.S.C. 102(b) as being anticipated by landolo. landolo teaches the genetic analysis of extra cellular toxins of *Staphylococcus aureus*. landolo teaches that it was well known in the art that there are active sites within the enterotoxins that reside in the N-terminal tryptic fragment (page 389 para. 5). The hypothesis was based on the sequence similarities exhibited by peptides of SEA, SEB and SEC₁. The extension of the analysis to other enterotoxins shows striking amino acid similarity among enterotoxins A, B, C₁, D and E in the region immediately downstream from the cysteine located at residue 106 in SEA (page 390 para. 1). See Table 2 that shows sequence similarities among the pyrogenic toxins and enterotoxins. In particular see the consensus sequence, which has sequence identity to SEQ ID NO:34.

The prior art peptide appears to be the same as that claimed or an obvious variant. The prior art peptide appears to possess the same or similar functional characteristics. Since the Patent Office does not have the facilities for examining and comparing applicants' peptide with the peptide of the prior art reference, the burden is upon the applicants to show an unobvious distinction between the material structural

Art Unit: 1645

and functional characteristics of the claimed peptide of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Therefore, landolo teach the peptide and a sequence that consist essentially of SEQ ID NO:34, which is a component of a larger molecule as claimed by the instant application.

Response to Arguments

9. Applicant's arguments filed July 6, 2001 have been fully considered but they are not persuasive.

The rejection of claims 54-55 under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention is maintained. See also the 35 U.S.C. 101 rejection above. Applicants state that the amendments are sufficient to ensure the subject matter of claims 50-55 are not products of nature. However it is the examiner's position that the amendments are not sufficient. The claims must recite the appropriate language to alleviate the product of nature rejections. Therefore the rejection is maintained.

Allowable Subject Matter

10. It should be noted that SEQ ID NO:3 is free of the prior art.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ja-Na A Hines whose telephone number is

Art Unit: 1645

703-305-0487. The examiner can normally be reached on Monday-Thursday and alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

Ja-Na Hines *JN*

February 26, 2002

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER